IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

ESBARDA CHAPA,

Plaintiff,

v. **Civil Action No. 2:13-cv-17511**

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Summary Judgment)

Pending before the court is Defendant Boston Scientific Corporation's Motion for Summary Judgment and Memorandum in Support Against Plaintiff Esbarda Chapa ("Motion") [Docket 58]. As set forth below, BSC's Motion is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, strict liability for design defect, negligent manufacturing, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose. BSC's Motion is **DENIED IN PART** with respect to whether the plaintiff's claims are time-barred by the statute of limitations and the claims of strict liability for failure to warn, negligent failure to warn, and negligent design.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than

75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Chapa's case was selected as a Wave 1 case by BSC.

On October 12, 2009, Ms. Chapa was surgically implanted with the Pinnacle Pelvic Floor Repair Kit (the "Pinnacle"), a product manufactured by BSC to treat POP. (*See* Mot. [Docket 58], at 1–2). Dr. Kathleen Sears implanted the product at Covenant Medical Center in Lubbock, Texas. (Short Form Compl. [Docket 1], at 4). Ms. Chapa claims that as a result of implantation of the Pinnacle, she has experienced multiple complications. She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breach of express and implied warranties; and punitive damages. (*Id.*).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the

evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict" in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, I generally refer to the choice-of-law rules of the jurisdiction where the plaintiff first filed her

claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Chapa did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Chapa received the Pinnacle implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Texas law to the plaintiff's claims. In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws (Am. Law Inst. 1971). *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under section 145 of the Restatement (Second) of Conflict of Laws, the court must apply the law of the state with the most "significant relationship to the occurrence and the parties." Here, Ms. Chapa resides in Texas, and the product was implanted in Texas by a Texas physician. Thus, I apply Texas's substantive law to this case.

III. Analysis

BSC argues that it is entitled to summary judgment because Ms. Chapa's legal theories are without evidentiary or legal support. (Mot. [Docket 58], at 1). Ms. Chapa concedes her claims for (1) strict liability for design defect, (2) strict liability for manufacturing defect, (3) negligent manufacturing, (4) breach of express warranty, and (5) breach of implied warranty. (*See* Pl.'s Resp. in Opp'n to Def.'s Mot. for Summ. J. ("Resp.") [Docket 69], at 1). Accordingly, BSC's Motion on these claims is **GRANTED**. Below, I apply the summary judgment standard to the remaining claims.

A. Statute of Limitations

BSC first argues that each of the plaintiff's personal injury claims are barred by Texas's statute of limitations. (Mot. [Docket 58], at 5–6). Under Texas law, the statute of limitations for personal injury actions is two years. Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a). Accordingly, a plaintiff must file her claims within two years of the date the alleged wrongful act caused her injury. *Childs v. Haussecker*, 974 S.W.2d 31, 36 (Tex. 1998). This period, however, may be tolled by application of the discovery rule. The discovery rule tolls accrual "until a plaintiff knows or, through the exercise of reasonable care and diligence, should have known of the wrongful act and resulting injury." *Id.* (internal quotations and citation omitted); *see also Woodruff v. A.H. Robbins Co.*, 742 F.2d 228, 230 (5th Cir. 1984) ("[T]he Texas discovery rule . . . provides that certain 'inherently undiscoverable causes of action' do not accrue until the plaintiff learns or reasonably should have learned of the negligent cause . . . .").

Ms. Chapa filed this action on July 5, 2013. (Short Form Compl. [Docket 1]). BSC argues that Ms. Chapa knew or should have known of the wrongful act and resulting injury in 2010 or early 2011, when Ms. Chapa began to experience chronic pelvic pain, incontinence, erosion, and

dyspareunia, none of which she says she experienced before the October 12, 2009 surgery. (Mot. [Docket 58-1], at 6 (citing Chapa Dep., Ex. F [Docket 58-1], at 67:4-68:1)). On her Plaintiff Fact Sheet, however, Ms. Chapa indicates that she believed her initial bodily injuries could be attributed to her "personally," or were "perhaps caused by some other factor besides the mesh." (Pl. Fact Sheet [Docket 69-2], at 7). In fact, Dr. Sears—her own treating physician—informed Ms. Chapa that it could be "just because, […], you are getting used to the surgery." (Chapa Dep. [Docket 69-3], at 67:13-15). Consequently, Ms. Chapa "had no reason to suspect the mesh to be defective and root cause of these problems." (Pl. Fact Sheet [Docket 69-2], at 7).

This determination is plainly a fact question left to the jury. *See Childs*, 974 S.W.2d at 44 ("Inquiries involving the discovery rule usually entail questions for the trier of fact."). On this reasoning, and bearing in mind my duty to draw all legitimate inferences in favor of the nonmovant, I **DENY** BSC's Motion with respect to the statute of limitations.

B. Strict Liability

Texas has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts. *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and

> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A. "The concept of defect is central to a products liability action brought on a strict tort liability theory, whether the defect be in conscious design, or in the manufacture of the product, or in the marketing of the product." *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

1. Statutory Defense

BSC argues that Chapter 82 of the Texas Civil Practice and Remedies Code provides two separate statutory presumptions of non-liability that apply to FDA-regulated prescription medical devices, both of which bar Ms. Chapa's claim for strict liability failure to warn. (Mot. [Docket 58], at 9–13). Section 82.008(a) of the Texas Civil Practice and Remedies Code states that:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design *complied with mandatory safety standards or regulations* adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

Tex. Civ. Prac. & Rem. Code § 82.008(a) (emphasis added).

As I have previously held, the 510(k) process is not a safety statute or administrative regulation. *See generally Lewis, et al. v. Johnson & Johnson, et al.*, 991 F. Supp. 2d 748 (S.D. W. Va. 2014). The Supreme Court determined that "the 510(k) process is focused on equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493, 116 S. Ct. 2240 (1996) (internal quotation omitted); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323, 128 S. Ct. 999 (2008) ("While § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not

equivalence.") (internal quotation omitted).[1] FDA regulations also state that 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the FDA. *See id.* ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."). Because the FDA's 510(k) clearance process is not a mandatory safety standard or regulation, I **FIND** section 82.008(a) inapplicable here.

Section 82.008(c) of the Texas Civil Practice and Remedies Code provides as follows:

> In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that *after full consideration of the product's risks and benefits the product was approved or licensed* for sale by the government or agency.

Tex. Civ. Prac. & Rem. Code § 82.008(c) (emphasis added). The FDA conducts a full analysis of the product's risks and benefits when a product goes through the premarket approval process, not the 510(k) clearance process. As discussed above, the 510(k) process relates to a medical device's equivalence to a preexisting device; it does not require "full consideration of the product's risks

[1] Other courts interpreted *Lohr* as I do, holding that the 510(k) process does not go to whether a product is safe and effective or impose any requirements on its own. *See, e.g.*, *Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001); *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 985 (D. Minn. 2012); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 n.6 (E.D. Pa. 2007); *Nicoll v. I-Flow, LLC*, No. 12-1593, 2013 WL 2477032, at *3 (E.D. La. June 7, 2013).

and benefits." Also, as stated above, 510(k) clearance does not constitute FDA "approval" of the device. Therefore, I **FIND** that section 82.008(c) does not apply to BSC in this case.

C. Negligence

The defendant has not presented arguments with respect to the negligent design defect and negligent failure to warn claims beyond those I have already rejected. Accordingly, BSC's Motion as to the negligent design defect and negligent failure to warn claims is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 58] is **GRANTED IN PART** with respect to the plaintiff's claims of strict liability for manufacturing defect, strict liability for design defect, negligent manufacturing, breach of express warranty, breach of implied warranty of merchantability, and breach of implied warranty of fitness for a particular purpose, and **DENIED IN PART** with respect to whether the plaintiff's claims are time-barred by the statute of limitations and the claims of strict liability for failure to warn, negligent failure to warn, and negligent design.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 4, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE